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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/052,323	TANG ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-17,20-26,28-32,35-40,42 and 43* is/are pending in the application.

4a) Of the above claim(s) *3,7,8 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,9-17,21-26,28-32,35-40,42-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 7/5/07 was entered for the purpose of a compact prosecution even though the status identifiers for pending claims 3, 7-8 and 20 were incorrect. Their status identifiers should be "Withdrawn" because they were withdrawn from further consideration in the previous Office action mailed on 1/5/07 because they are directed to a non-elected species.

Claims 1, 3-4, 6-17, 20-26, 28-32, 35-40 and 42-43 are pending in the present application.

Applicants previously elected *Escherichia* as a species of the bacterial vector.

Accordingly, claims 1, 4, 6, 9-17, 21-26, 28-32, 35-40 and 42-43 are examined on the merits herein with the aforementioned elected species.

Examiner's Remark

1. Applicants requested an interview prior to issuance of any paper other than a Notice of Allowance in the form of a paragraph on page 9 in the Amendment filed on 7/5/07. It is noted that Applicants have not specified which particular issues to be discussed in the interview. Additionally, due to time constraint because a response to Applicant's amendment filed on 7/5/07 has to be mailed out within 2 months, the above request for an interview is not possible. However, after receiving this Office action should Applicants still desire to have an interview, please contact with the undersigned Examiner to schedule for a suitable date and time for such an interview.

2. In the Amendment filed on 7/5/07, it is noted that on page 6, second paragraph, Applicants state "**Claims 16, 25, 32 and 43 have been cancelled herein**,....as to equivalents". However, the presented set of claims is not consistent with such statement.

Priority

The present application is a continuation-in-part of U.S. Serial No. 09/563,826, filed 5/31/00, now US Patent 6,348,450; which claims benefit to 60/132216, filed on 5/3/1999; and is a continuation-in-part of U.S. Serial No. 09/533,149, filed 3/23/00, now US Patent 6,716,823; which is a continuation-in-part of U.S. Serial No. 09/402,527, filed 01/03/2000, now US Patent 6,706,693; which is a 371 national stage entry of PCT/US98/16739, filed on 8/13/1998; which claims benefit to provisional applications 60/055,520, filed on 8/13/1997 and 60/075,113, filed on 2/11/1998.

Upon review of the specifications of the above non-provisional U.S. applications and the above provisional applications and comparison with the specification of the present application, it is determined that while claims 1, 9-16, 21-24, 26, 28-29, 32, 35-39 and 42-43 may be entitled to the priority date of 08/13/1997, claims 4, 6, 17, 25, 30-31 and 40 are only entitled to the priority date of 1/18/02. This is because the concept of using a bacterial vector which is ***Escherichia* or any live gram negative bacterium or any bacterium (a living entity)** in the methods as claimed is first described in the specification of the present application. The examiner further notes that any plasmid vector can be considered to be a "bacterial vector" because a plasmid vector contains

bacterial sequences and it is propagated and selected in bacteria using a selective marker.

Claim Objections

Claim 43 is still objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new ground of rejection necessitated by Applicant's amendment.***

Claim 32 recites the limitation "multiple applications of **the delivery device** including the vector" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim. This is because in claim 26, 21 and 1 from which claim 32 is dependent on, there is no recitation of any delivery device. Therefore, which particular or specific delivery device do Applicants refer to? The metes and bounds of the claim

are not clearly determined, therefore it is uncertain which prior art would meet or would not meet the claim limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9-15, 21-23, 26, 28-29, 38 and 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Roop et al. (US 6,143,727 with the effective filing date of at least 11/1/1993) for the same reasons already set forth in the Office action mailed on 1/5/07 (pages 5-6). ***The same rejection is restated below.***

Roop et al already teaches a method for inducing an immunogenic or immunological response in an animal or human by transforming epidermal cells with a vector construct targeted for expression in epidermal cells (see at least col. 11, lines 5-15; cols. 25-26; col. 10, lines 29-36). The vector construct contains genetic material coding for any viral capsid protein, bacterial proteins, parasitic organisms and toxins or other factors which might produce an immunogenic or immunological responses such as tumor antigens, tumor suppressors, oncogenes, IL-1, IL-6, IL-8 and others (col. 5, line 64 continues to line 15 of col. 6). Roop et al further teaches that the vector

construct includes a plasmid, a cosmid, a viral vector and others (col. 5, lines 33-48). Please note that a plasmid vector can be considered to be a "bacterial vector" because a plasmid vector contains bacterial sequences and it is propagated and selected in bacteria using a selective marker. Roop et al also discloses that the vector construct can be administered (a device must be used for administration) into skin tissue by liposomes, calcium phosphate-coprecipitated DNA, DNA coupled to macromolecular complexes and other forms by various routes of delivery that include topical administration, intravenous, intramuscular and others (col. 11, lines 31-51; col. 21, line 66 continues to line 29 of col. 22). Roop et al discloses specifically that topical administration of the vectors is advantageous since it allows localized concentration at the site of administration with minimal systemic adsorption, simplified delivery strategy and reduced the extent of toxicological characterization (col. 22, lines 19-29).

Accordingly, the teachings of Roop et al meet every limitation of the claims as written. Therefore, the reference anticipates the instant claims.

Claims 1, 9-15, 21-23, 26, 28-29, 38 and 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Carson et al. (US 5,679,647 with the effective filing date of at least 11/3/1994; IDS) for the same reasons already set forth in the Office action mailed on 1/5/07 (pages 6-7). ***The same rejection is restated below.***

Carsons et al discloses methods for administering biologically active peptides to a host (including any vertebrate, a mammal, a human or a domestic livestock or pet animal; see col. 6, liens 11-15) by introducing one or more naked polynucleotides

encoding the peptides by non-invasive means, including a method for immunizing a host against one or more antigens such as tumor-associated antigens or NP gene from an H1AN1 strain of influenza virus (see at least col. 1, lines 24-34; col. 34, lines 25-26 and the claims). Non-invasive means include dermal and epidermal administrations which are routes of delivery that apply the naked polynucleotides to or through skin (col. 6, lines 31-39). Carsons et al specifically teaches that where the naked polynucleotides are to be introduced into skin, delivery of the polynucleotides is preferably facilitated without need for injection by use detergents, absorption promoters, chemical irritants or mechanical irritants or by transdermal transmission by iontophoresis with appropriate devices containing the naked polynucleotides (col. 9, lines 26-38; col. 19, line 3 continues to line 10 of col. 20). Carsons et al also specially discloses that the naked polynucleotides can be in the form of plasmid DNA vectors (col. 12, liens 36-45; col. 13, lines 54-62). Please note that a plasmid vector can be considered to be a "bacterial vector" because a plasmid vector contains bacterial sequences and it is propagated and selected in bacteria using a selective marker.

Accordingly, the teachings of Carsons et al meet every limitation of the claims as written. Therefore, the reference anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 16-17, 24-25, 30-31, 35-37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Powell et al (US 5,877,159) or WO 01/89535 A1 in view of Roop et al. (US 6,143,727 with the effective filing date of at least 11/1/1993) for the same reasons already set forth in the Office action mailed on 1/5/07 (pages 8-11). ***The same rejection is restated below.***

With respect to the elected species, Powell et al already teaches a method for introducing and expressing a gene (encoding a vaccine antigen or a therapeutic gene or an immunoregulatory gene) in animal cells (mammals, humans, goat, feline, canine, ovine, equine), including *in vivo*, by infecting the animal cells with live invasive bacteria such as *Escherichia coli* containing a eukaryotic expression cassette encoding said gene (see at least the abstract and Summary of the Invention; col.. 7, line 56 continues to line 4 of col. 8; col. 8 line 48). The vaccine antigen may be a protein or antigenic fragment thereof from viral pathogens, bacterial pathogens, and parasitic pathogens,

including fragment C of tetanus toxin of Clostridium tetani (col. 17 and particularly lines 40-42). The eukaryotic expression cassettes encoding vaccine antigens can also be delivered in combination with eukaryotic expression cassettes encoding immunoregulatory molecules or other proteins (col. 19, lines 28-32). Powell et al further teaches that the invasive bacteria containing the eukaryotic expression cassettes can be introduced to infect the animal by intradermal, intramuscular and others (col. 19, lines 36-54).

WO 01/89535 A1 also teaches a method for introducing and expressing a gene (encoding a vaccine antigen or a therapeutic gene or an immunoregulatory gene) in animal cells (mammals, humans, goat, feline, canine, ovine, equine), including *in vivo*, by infecting the animal cells with bacterial blebs from *Escherichia* containing a eukaryotic expression cassette encoding said gene (see at least the abstract and Summary of the Invention; pages 4-5; page 18; last paragraph of page 24 continues to first paragraph of page 25). Since the bacterial blebs or minicells can contain bacterial chromosome and/or plasmid DNA, they can be considered to be a modified version of live bacterial cells (page 5, top of second paragraph). The vaccine antigen may be a protein or antigenic fragment thereof from viral pathogens, bacterial pathogens, and parasitic pathogens including fragment C of tetanus toxin of Clostridium tetani (page 40, bottom of first paragraph), and that eukaryotic expression cassettes encoding vaccine antigens can also be delivered in conjunction with additional expression cassettes encoding known adjuvants such as IL-12, bacterial lipopolysaccharide or lipid A (page 38-41). WO 01/89535 A1 further teaches that the bacterial blebs containing the

eukaryotic expression cassettes can be introduced to infect the animal by intradermal, intramuscular or any other suitable administration or inoculation routes (page 47, second paragraph).

Neither Powell et al nor WO 01/89535 A1 discloses specifically that live invasive bacteria such as *Escherichia coli* containing a eukaryotic expression cassette encoding a vaccine antigen or bacterial blebs (minicells) from *Escherichia* containing the eukaryotic expression cassettes, respectively, can be introduced to infect an animal by topical application, even thought the references disclose a variety of administration routes and particularly WO 01/89535 A1 teaches specifically that any other suitable administration or inoculation routes can be used.

At the filing date of the present application, Roop et al already teaches a method for inducing an immunogenic or immunological response in an animal or human by transforming epidermal cells with a vector construct targeted for expression in epidermal cells (see at least col. 11, lines 5-15; cols. 25-26; col. 10, lines 29-36). Roop et al discloses specifically that topical administration of the vectors is advantageous since it allows localized concentration at the site of administration with minimal systemic adsorption, simplified delivery strategy and reduced the extent of toxicological characterization (col. 22, lines 19-29).

Accordingly, it would have been obvious for an ordinary skilled artisan to modify the method of either Powell et al or WO 01/89535 by topical applying live invasive bacteria such as *Escherichia coli* containing a eukaryotic expression cassette encoding a vaccine antigen or bacterial blebs (minicells) from *Escherichia* containing the

eukaryotic expression cassettes, respectively, to infect an animal in light of the teachings of Roop et al.

An ordinary skilled artisan would have been motivated to carry out the above modification because of the advantages offered by topical administration taught by Roop et al. The modified method is indistinguishable from the claimed method because it has the same method steps and starting materials as claimed.

An ordinary skilled artisan would also have a reasonable expectation of success in light of the teachings of either Powell et al. or WO 01/89535 and Roop et al., coupled with a high level of skill for an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 1, 29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Carson et al. (US 5,679,647 with the effective filing date of at least 11/3/1994; IDS) or Roop et al. (US 6,143,727 with the effective filing date of at least 11/1/1993) in view of either Alexander et al. (Human Mol. Genetics 4:2279-2285, 1995; IDS) or Li et al. (Nature Med. 1:705-706, 1995; IDS) for the same reasons already set forth in the Office action mailed on 1/5/07 (pages 11-14). ***The same rejection is restated below.***

Carsons et al discloses methods for administering biologically active peptides to a host (including any vertebrate, a mammal, a human or a domestic livestock or pet animal; see col. 6, liens 11-15) by introducing one or more naked polynucleotides

encoding the peptides by non-invasive means, including a method for immunizing a host against one or more antigens such as tumor-associated antigens or NP gene from an H1AN1 strain of influenza virus (see at least col. 1, lines 24-34; col. 34, lines 25-26 and the claims). Non-invasive means include dermal and epidermal administrations which are routes of delivery that apply the naked polynucleotides to or through skin (col. 6, lines 31-39). Carsons et al specifically teaches that where the naked polynucleotides are to be introduced into skin, delivery of the polynucleotides is preferably facilitated without need for injection by use detergents, absorption promoters, chemical irritants or mechanical irritants or by transdermal transmission by iontophoresis with appropriate devices containing the naked polynucleotides (col. 9, lines 26-38; col. 19, line 3 continues to line 10 of col. 20). Carsons et al also specially discloses that the naked polynucleotides can be in the form of plasmid DNA vectors (col. 12, liens 36-45; col. 13, lines 54-62). Please note that a plasmid vector can be considered to be a "bacterial vector" because a plasmid vector contains bacterial sequences and it is propagated and selected in bacteria using a selective marker.

Roop et al already teaches a method for inducing an immunogenic or immunological response in an animal or human by transforming epidermal cells with a vector construct targeted for expression in epidermal cells (see at least col. 11, lines 5-15; cols. 25-26; col. 10, lines 29-36). The vector construct contains genetic material coding for any viral capsid protein, bacterial proteins, parasitic organisms and toxins or other factors which might produce an immunogenic or immunological responses such as tumor antigens, tumor suppressors, oncogenes, IL-1, IL-6, IL-8 and others (col. 5,

line 64 continues to line 15 of col. 6). Roop et al further teaches that the vector construct includes a plasmid, a cosmid, a viral vector and others (col. 5, lines 33-48). Please note that a plasmid vector can be considered to be a "bacterial vector" because a plasmid vector contains bacterial sequences and it is propagated and selected in bacteria using a selective marker. Roop et al also discloses that the vector construct can be administered (a device must be used for administration) into skin tissue by liposomes, calcium phosphate-coprecipitated DNA, DNA coupled to macromolecular complexes and other forms by various routes of delivery that include topical administration, intravenous, intramuscular and others (col. 11, lines 31-51; col. 21, line 66 continues to line 29 of col. 22). Roop et al discloses specifically that topical administration of the vectors is advantageous since it allows localized concentration at the site of administration with minimal systemic adsorption, simplified delivery strategy and reduced the extent of toxicological characterization (col. 22, lines 19-29).

Neither Carsons et al nor Roop et al. teaches specifically the step of removing the skin prior to applying the delivery device containing the bacterial vector to the skin of the animal.

However, Alexander et al already discloses a method of gene transfer and expression via topical application in which skins were shaved and treated with a depilatory cream to remove hairs (page 2284, left-hand column, third paragraph).

Similarly, Li et al also discloses a method of gene transfer and expression via topical application in which skins were preshaved (see at least the abstract and page 706, left-hand column, second paragraph).

Accordingly, it would have been obvious for an ordinary skilled artisan to modify either the method of Carson et al. or Roop et al. by also shaving skins or treating skins with a depilatory cream to remove hair prior introducing non-invasively the naked polynucleotides or plasmid vector constructs present in the appropriate devices into skin in light of the teachings of either Alexander et al. or Li et al.

An ordinary skilled artisan would have been motivated to carry out the above modification because conventional successful, non-invasive, topical application methods at the effective filing date of the present application involve pretreatment of the skin to remove hair as taught by either Alexander et al. or Li et al.

An ordinary skilled artisan would also have a reasonable expectation of success in light of the teachings of either Carson et al. or Roop et al. and either Alexander et al. or Li et al., coupled with a high level of skill for an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Response to Arguments

Applicants' arguments related to the above rejections in the Amendment filed on 7/5/07 (pages 7-8) have been fully considered but they are respectfully not found persuasive for the reasons discussed below.

Applicants simply argue that both Roop and Carson relate to the administration of plasmid vectors, not "bacterial vectors" as is required by the pending claims.

Applicants further argue one of skill in the art is certainly aware that plasmid vectors are small circular molecules of double stranded DNA derived from natural plasmids that occur in bacterial cells, and not bacterial vectors. Rather the term "bacterial vector" is used to indicate a vector comprising a bacteria, which bacteria can contain and express a nucleic acid molecule encoding a gene product of interest; and a plasmid vector can not be considered a bacteria vector as it does not encompass the bacteria itself.

It is noted that on page 17, the instant specification states "Specifically, **the bacterial vectors, accordingly to the present invention, are preferably gram-negative bacteria which can invade mammalian hosts**". On the basis of this statement, the term "a bacteria vector" is not necessarily limited only to **a live bacterium** as argued by Applicants. It is also well known in the art that any ordinary skilled artisan would consider a plasmid vector is a "bacterial vector" because a plasmid vector contains bacterial sequences and it is propagated and selected in bacteria using a selective marker. This interpretation is also consistent with the term "a vector" as defined by the instant specification on page 15, fourth paragraph, as a tool that allows or facilitates the transfer of an entity from one environment to another, and a vector includes a viral vector, a bacterial vector, a protozoan vector, a DNA vector, or a recombinant thereof.

It is also noted that Applicants failed to provide substantial arguments regarding to the 103 rejection based on either Powell et al (US 5,877,159) or WO 01/89535 A1 in view of Roop et al. (US 6,143,727 with the effective filing date of at least 11/1/1993).

Accordingly, the claims are still rejected for the rejections of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 9-15, 21-23, 26, 28-29, 38-39 and 42-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,706,693 for the same reasons already set forth in the Office action mailed on 1/5/07 (page 15). ***The same rejection is restated below.***

Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of non-invasively inducing a systemic immune response or a protective systemic immune response, comprising topically administering, a plasmid DNA and liposome complex vector that encodes a gene of interest and expresses a protein encoded by the gene of interest, to the skin of a mammal, in an effective amount to induce said systemic immune response to said protein of the issued U.S. Patent 6,706,693 anticipates the claimed genus (a method of non-invasive immunization in an animal and/or a method of inducing a systemic immune response or

systemic therapeutic response to a gene product, in an animal, comprising contacting skin of the animal with a bacterial vector that contains and expresses a nucleic acid molecule encoding the gene product, in an amount effective to induce the response) in the application being examined and, therefore, a patent to the genus would, necessarily, extend the rights of the species or sub- should the genus issue as a patent after the species of sub-genus. Please note that any plasmid DNA vector can be considered to be a "bacterial vector" because a plasmid vector contains bacterial sequences and it is propagated and selected in bacteria using a selective marker.

Claims 1, 4, 6, 9-17, 21-26, 28-32, 35-40 and 42-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/346,021 for the same reasons already set forth in the Office Action mailed on 9/9/05 (pages 5-6).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 11-13, 25, 28-29 and 38-39 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 6-8, 20, 23-24 and 33-34 of copending Application No. 10/116,963 for the same reasons already set forth in the Office action mailed on 1/5/07 (page 16).

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It is noted that Applicants simply traversed the provisional double patenting rejections over co-pending Applications 10/346,021 and 10/116,963. **It is further noted that Applicants failed to address the obviousness-type double patenting rejection as being unpatentable over claims 1-3 of U.S. Patent No. 6,706,693**.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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QUANG NGUYEN PH.D.
PRIMARY EXAMINER